BROOKHAVEN NATIONAL LABORATORY GENERAL CLILNICAL RESEARCH CENTER POLICY	GCRC POLICY: IC-02	PAGE 1 OF3
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SUBJECT: Pharmacy	REVIEWED BY: W. Gunther	GCRC Manager
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	EFFECTIVE DATE: 7/1/05	
	REVISION HISTORY: 3	

1.0 PURPOSE

The Pharmacy compounds and dispenses drugs for internal, external and parenteral applications. This document sets forth requirements which prevent contamination of drugs and solutions.

2.0 POLICIES

1. There shall be an effective infection prevention program in the Pharmacy to ensure sterility of drugs and solutions.
2. Only authorized personnel in the department shall be allowed to prepare drugs or solutions for subject use.
3. Specific pharmaceutical procedures shall be developed by the Pharmacist relating to admixtures and drug reconstitution, and the preparation of intravenous and irrigating fluids.

3.0 RESPONSIBILITIES

1. Authorized personnel are responsible for preventing contamination of drugs and parenteral and irrigation solutions.
2. In the event a recall of any item is declared, the Pharmacist, on a working day or as soon as possible, will inform the authorized personnel. The authorized personnel will then be responsible for identification, collection and processing of the required item(s).

4.0 PROCEDURES

1. PERSONNEL: Only authorized personnel are permitted to prepare drugs or solutions prescribed for subject use.
    A. Wash hands before and after handling drugs and solutions.
    B. Clean laboratory coat/gown is worn at all times in the Pharmacy.
    C. Personnel with respiratory infections or dermatological diseases are not permitted to handle open solution containers or come into contact with medications in the Pharmacy.
    D. No eating or smoking is allowed in the Pharmacy.

5.0 PREPARATONS

1. Preparation of oral products including tablets, capsules, liquid medication and enteral feeding.
    A. Use aseptic technique for preparation, including:
        1. Wash hands before mixing, packing, or dispensing drugs.
        2. Use no-touch procedures for counting tablets or capsules.
        3. Use clean equipment for mixing powders.
        4. Use prepackaged unit doses when available to facilitate clean dispensing.

    Bulk compounding and packaging of oral solutions:
        1. Use aseptic techniques for preparation (see #1) using sterile diluent
        2 Package in UNIT DOSE containers whenever possible
        3. Label unopened, refrigerated products for 6 month expiration
        4. Each unit, once opened, must be used within 24 hours and then discarded
        5. Maintain compounding log indicating products used, manufacturer, and expiration date, with signature and date of compounding
        6. Oral products that are repackaged will have an expiration date of 1 year or if the manufacturer date is less than 1 year, ½ of that time.
2. Preparation of medications for ingestion or topical application such as ointments, powders, and topical solutions
    A. Are the same used for oral preparation with the following additions.
        1. Use sterile diluents.
        2. Use unit dose where possible.
        3. Date solutions and discard when expired.
3. Preparation of products which may be administered by injection into skin and tissues via intramuscular, subcutaneous, or intradermal routes, intravenous route, or into body cavities or organs.

A. Use aseptic technique for preparation.
   1. Wash hands before preparing or drawing up into syringe.
   2. Use sterile supplies:
      a. Needles and syringes (dispose in puncture resistant containers).
      b. Water/saline for solution.
   3. Cleanse all injection ports with antimicrobial agent prior to entry.
   4. Use storage appropriate for product.
      a. Indicate expiration date clearly.
      b. Refrigerate (if appropriate)
      c. Define expiration time or date by which mixed products must be used.

4. Preparation of parenteral solution such as large volumes for intravenous fluid replacement, nutritional fluids (TPN) which contain proteins, high glucose concentrations, vitamins, mineral elements, fats, and small-volume solutions to provide medications (admixture/minibags).
   1. Examine all shipments for signs of rough handling and/or breakage (e.g., water marks) and return to the manufacturer if defective.
   2. Avoid temperature extremes in storage area.
   3. Handle package carefully.
   4. Select a low-traffic area for medication preparation.
   5. Use laminar airflow hoods for preparation of parenteral products to reduce airborne contamination.
      a. Hood should be inspected and certified by qualified personnel every 12 months.
      b. Keep objects inside the hood at a minimum because they can cause air turbulence.
      c. Work at least 15 cm (=6") inside the hood.
      d. Wipe hood surfaces (except filter surface) with sterile 70%-90% ethyl or isopropyl alcohol before each use and several times daily when the hood is in continuous use.
   6. Provide convenient sinks for handwashing.
   7. Use an antimicrobial agent for handwashing prior to mixing parenteral solutions.
   8. Check containers for cracks, leaks, turbidity and particulate matter which may indicate contamination.
      a. Use a light-device to check IV solutions for dark particulate matter.
      b. Use a dark background to check for fungal particles.
      c. Light sensitive solutions shall be protected from light

NOTE: Many intravenous solution will not be cloudy even with bacterial concentrations of 10^5 organisms/ml.

   9. Consider special clothing for personnel preparing parenteral solutions.
      • The CDC recommends gloves, gown and mask be worn when mixing large batches of IV solutions.
   10. Avoid use of multidose vials.
      a. Use single-use vials whenever possible and discard after use.
      b. Affix label to the (vial) container, which contains the date the multidose vial, was opened, the expiration date and the initials o f the person who opened the vial.
      c. Refrigerate multidose vials unless contraindicated by the manufacturer (cold temperatures may inhibit activity of some preservatives).
      d. Discard multidose vials according to manufacturer's instructions. If there are no manufacturer's instructions discard the multidose vials with preservative within 28days, without preservative within 24 hours.
      e. Use contents of large-volume containers within 24 hours after opening.
      f. All open vials found which do not have the date and initials of person puncturing shall be immediately discarded.
   11. Label solutions to identify product for recall or to identify suspected source of contamination. Label includes:
      a. The additive.
      b. Dosage of additive.
      c. Expiration date.
      d. Date of preparation and identification of personnel performing admixing.
   12. Monitor storage of solutions.
      a. Refrigerate all admixed fluids or use within 6 hours of admixture (refrigeration will inhibit growth of microorganism).

b. If required, store admixed solutions in the refrigerator.

NOTE: Refrigeration must begin immediately after admixture.

i. Use storage temperatures which are product-specific.

ii. Keep a log of daily temperature checks using a NIST thermometer

iii. All solutions shall be stored with the earliest expiring items in front, with the later expiring items in corresponding order behind.

13. Maintain integrity of product prior to subject use.
    a. Keep cover on after opening irrigation solution container to reduce risk of contamination.
    b. Continue refrigeration of admixture solutions prior to administration.
    c. Double check the label before administration
    d. Complete infusion within 24 hours of beginning administration to subject, or discard solution.

5. The custodial staff will follow IC-11.0
6. The housekeeping staff will follow IC-12.0

6.0 SATELLITE FACILITIES PHARMACY

A Principal Investigator may establish a satellite pharmacy, outside the GCRC Central Pharmacy, in order to store controlled substances. (CRC Policy8.3) The rules and regulations must be strictly enforced.

7.0 ATTACHMENTS

1. Label to be affixed to multidose vial

Attachment 1